DEC 1 9 2000

PHILIPS

Philips Medical Systems

K002942

510(k) Summary

Philips EasyVision Family Workstation Cardiac Scoring Option

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I General Information

Company Name:	Philips Medical Systems North America Company
Address:	710 Bridgeport Avenue, Shelton, CT 06484
Contact Person	Peter Altman
Telephone Number:	203-926-7031
Prepared (date):	2000-09-01
Device Name:	Philips Easy Vision Family Workstation Option Cardiac Scoring
Classification Name:	Computed tomography x-ray system (Accessory) 892.1750
Classification:	Class: II
ProCode:	90 JAK
Common/Usual Name:	Workstation
Predicate Devices:	Philips EasyVision Workstation Calcium Scoring Software Package for the Siemens 3Dvirtuoso workstation (K990426)

Philips Medical Systems
North America Company
710 Bridgeport Avenue
P.O. Box 860
Shelton, Connecticut 06484-0917
Tel: (203) 926-7674
Fax: (203) 929-6099

II Information Supporting Substantial Equivalence Determination

System Description:
The Cardiac Scoring option adds capabilities to the existing Philips EasyVision Family of workstations using images acquired from CT systems.
The Cardiac Scoring option on the EasyVision Workstation allows the user to mark detected calcification in acquired CT cardiac images, assign each detected area to a coronary artery and to calculate the Agatston score from this data. The user is aided in the detection of calcification with the use of a Maximum Intensity Projection of the selected stack of cardiac CT images. Results are displayed as Agatston score per artery as well as a total examination score.

Intended Use:
The Cardiac Scoring option is intended to be used to evaluate calcified plaques in the coronary arteries, which is a reported risk factor for coronary artery disease. Cardiac Scoring can be used as a tool to evaluate the amount of calcification with sequential scanning of patients and thereby show progression or regression of these calcifications, which maybe related to the prognosis of cardiac events related to coronary disease.

Safety information:
No new hazards are introduced by the addition of the Cardiac Scoring option to the EasyVision Workstation.

Substantial equivalence:
The Cardiac Scoring package is substantially equivalent to the Siemens Medical Systems Calcium Scoring option on the 3Dvirtuoso workstation (K990426).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2000

Mr. Peter Altman
Director of Regulatory Affairs
Philips Medical Systems North American Company
710 Bridgeport Avenue
P.O. Box 860
SHELTON CT 06484-0917

Re: K002942
Philips Easy Vision Family Workstation
Cardiac Scoring Option
Dated: September 20, 2000
Received: September 21, 2000
Regulatory Class: II
21 CFR §892.2050/Procode: 90 LLZ

Dear Mr. Altman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(K) Number (if known): K002942

Device Name: Philips EasyVision Family Workstation Cardiac Scoring Option

Indications for Use:

The Cardiac Scoring Option is intended for use with specified acquired CT cardiac image datasets. It is intended to evaluate calcified areas and produce a "score" by:

- User identification of calcified areas within coronary arteries
- User assignment of an identified area to a specific coronary artery
- Using the Hounsfield units within these classified areas to produce scores per artery as well as a total examination score

Such scores may be used as a tool to evaluate the amount of calcification with sequential scanning of patients and thereby show progression or regression of these calcifications, which may be related to the prognosis of cardiac events related to coronary disease.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002942

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)